

We Claim:

1. A monohydrochloride salt of risperidone.
2. The salt according to claim 1, wherein the ratio of risperidone ion to chloride ion is within the range of 0.8-1.2:1.
3. The salt according to claim 1, wherein the water solubility is less than 10 mg/ml.
4. The salt according to claim 3, wherein the water solubility is within the range of 5 to 9 mg/ml.
5. The salt according to claim 1 in crystalline form.
6. The salt according to claim 5, having a purity of at least 90%.
7. The salt according to claim 6, wherein said salt purity is at least 98%.
8. The salt according to claim 7, wherein said salt purity is at least 99%.
9. The salt according to claim 8, wherein said salt purity is at least 99.8%.
10. The salt according to claim 5, wherein said salt is a crystalline risperidone hydrochloride anhydrate.
11. The salt according to claim 10, which exhibits an x-ray powder diffraction pattern that substantially corresponds to Figure 2.
12. The salt according to claim 5, wherein said salt is a hydrate having from about 7 to about 9.5% of water.
13. The salt according to claim 5, wherein said salt is crystalline risperidone hydrochloride hemipentahydrate.
14. The salt according to claim 13, which exhibits an x-ray powder diffraction pattern that substantially corresponds to Figure 4.

15. A pharmaceutical composition comprising a risperidone monohydrochloride salt according to claim 1 and at least one pharmaceutically acceptable excipient.
16. The pharmaceutical composition according to claim 15, wherein said composition is a solid oral dosage and said risperidone salt is contained in an amount within the range of 0.1 to 20 mg, expressed in terms of the weight of risperidone base.
17. The pharmaceutical composition according to claim 16, wherein said risperidone salt is crystalline risperidone monohydrochloride hemipentahydrate.
18. The pharmaceutical composition according to claim 15, wherein said composition is a liquid dosage form that contains an effective anti-psychotic amount of said risperidone salt dissolved in a liquid excipient.
19. The pharmaceutical composition wherein said liquid excipient is water or a water and ethanol mixture.
20. The pharmaceutical composition according to claim 19, which further comprises sorbitol.
21. A process for making the salt according to claim 1, which comprises:
contacting a risperidone donor with a chloride ion donor in a solvent; and
optionally
precipitating a crystalline risperidone monohydrochloride salt.
22. The process according to claim 21, wherein said risperidone donor is risperidone base or salt thereof; said chloride ion donor is hydrochloric acid or a chloride salt; and said solvent contains at least 10% water.
23. The process according to claim 21, wherein said risperidone donor is a risperidone salt of a weak acid; said chloride ion donor is a chloride salt; said

solvent is at least 90% water; and said precipitating step forms crystalline risperidone hydrochloride hemipentahydrate.

24. The process according to claim 23, wherein said risperidone donor is risperidone acetate.
25. The process according to claim 21, wherein said solvent is water, ethanol or a mixture thereof.
26. A method for treating a psychotic disorder in a mammal, which comprises administering an effective anti-psychotic amount of the risperidone salt according to claim 1 to a mammal in need thereof.
27. A risperidone monohydrochloride hemipentahydrate.
28. A pharmaceutical composition comprising an effective anti-psychotic amount of a risperidone monohydrochloride according to claim 27 and at least one pharmaceutically acceptable excipient.
29. A risperidone monohydrochloride salt substantially free from a risperidone dihydrochloride salt.
30. The risperidone salt according to claim 29, wherein the amount of the risperidone dihydrochloride salt is not greater than 1% based on the total amount of risperidone salt.
31. A pharmaceutical composition comprising an effective anti-psychotic amount of the risperidone salt according to claim 30 and at least one pharmaceutically acceptable excipient.
32. The pharmaceutical composition according to claim 31, wherein said composition is a liquid dosage form.

33. The pharmaceutical composition according to claim 31, wherein said composition is a solid oral dosage form.